E 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

[EPA-HQ-OPP-2017-0466; FRL-9928-01-OCSPP]

Spirodiclofen; Rescinding Cancellation Order for Certain Pesticide Registrations

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

SUMMARY: In the *Federal Register* of November 19, 2021, EPA amended the effective date of the cancellation for the two spirodiclofen registrations, EPA Registration Nos. 10163-382 and 10163-383, as requested by the registrant (Gowan), for the two registrations from December 31, 2021, until June 30, 2022. This notice announces that EPA is rescinding the cancellation order based on the submission of outstanding data that facilitated the risk assessments and registration review decision for spirodiclofen, as well as the registrant's commitment to implement label changes that adequately address the Agency's risk concerns. The registrant has submitted an amended label for the sole end-use product (EPA Registration No. 10163-383) that reflects the risk mitigation proposed by the Agency.

**DATES:** This recission of the cancellation order for the two spirodiclofen registrations, EPA Registration Nos. 10163-382 and 10163-383 is effective [INSERT DATE OF PUBLICATION IN THE *Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Veronica Dutch, Pesticide Re-evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 566-2352; email address: *dutch.veronica@epa.gov* 

## **SUPPLEMENTARY INFORMATION:**

## I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of

stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0466, is available at *https://www.regulations.gov*. Additional information about the docket and visiting EPA for docket access, visit *https://www.epa.gov/dockets*.

## II. What action is the Agency taking?

This notice is being issued to rescind the cancellation order for the two spirodiclofen registrations (EPA Registration Nos. 10163-382 and 10163-383). Bayer CropScience had requested the voluntary cancellation of these registrations in August 2017, as an alternative to developing data required by the registration review data call-in for spirodiclofen, GDCI-124871-1883. The notice of receipt of the request to cancel was published in the *Federal Register* on October 3, 2017 (82 FR 46052) (FRL-9966-85). The Agency solicited public comment on the notice and received no comments.

The history of subsequent related FRN actions is summarized in the table below.

Table - Cancellation Actions for EPA Registration Nos. 10163-382 and 10163-383

FR Citation	Title	Effective date	Notes
FRL-9971-10,	Product Cancellation Order for	6/30/2019	
80 FR 60985,	Certain Pesticide Registrations		
12/26/2017	and Amendments to Terminate		
	Uses		
FRL-9975-97,	Product Cancellation Orders:	12/31/2020	This notice amended the
83 FR 16076,	Certain Pesticide Registrations		previous order to correct an
4/13/2018	and Amendments to Terminate		error in the effective date
	Uses; Correction		
FRL-10017-47,	Product Cancellation Order for	12/31/2021	This notice extended the
85 FR 83078,	Certain Pesticide Registrations		cancellation effective date
12/21/2020			for the two spirodiclofen
			registrations to allow time
			for generating the
			outstanding data from GDCI-
			124871-1883

FRL-9272-01,	Product Cancellation Order for	6/30/2022	This notice extended the
86 FR 64929,	Certain Pesticide; Amendment		cancellation effective date
11/19/2021			for the two spirodiclofen
			product registrations to allow
			time for developing the
			spirodiclofen registration
			review risk assessments
FRL-9928-01	Spirodiclofen; Rescinding	[INSERT	This notice rescinds the
[INSERT DATE	Cancellation Order for Certain	DATE OF	cancellation order for the two
OF	Pesticide Registrations	PUBLICATIO	spirodiclofen product
PUBLICATION		N IN THE	registrations
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REGISTER]			

A history of subsequent related actions is summarized here. The Agency issued the spirodiclofen registration review generic data call-in (GDCI-124871-1883) on May 11, 2016. Bayer CropScience requested the voluntary cancellation of spirodiclofen as an alternative to developing the required data. The two spirodiclofen registrations were transferred from Bayer CropScience to Gowan Company effective March 18, 2021, and Gowan requested that the cancellation order be amended to facilitate the submission of outstanding data identified in the GDCI before the cancellations would become effective. Based on data submitted by both Bayer and Gowan to fulfill the requirements of the DCI, EPA subsequently completed draft ecological and human health risk assessments (DRAs) for the registration review of spirodiclofen. The DRAs were published for public comment on October 29, 2021 and identified potential risks of concern associated with the use of spirodiclofen. EPA subsequently extended the effective date of cancellation to allow time for developing the proposed interim registration review decision (PID) for spirodiclofen. On April 4, 2022, EPA issued a PID addressing the human health and ecological risks of concern identified in the spirodiclofen DRAs and proposing measures to mitigate those risks. Gowan subsequently submitted an amended end-use product label that is responsive to the risk mitigation measures proposed by EPA. The comment period on the PID closed on June 6, 2022. The Agency intends to issue an Interim Decision (ID) for spirodiclofen after considering comments received on the PID. Because the cancellation order for the

spirodiclofen product registrations was set to take effect on June 30, 2022, and because Gowan

has acted in good faith to address the Agency's risk concerns and Gowan has submitted an

amended label for the sole end-use product (EPA Registration No. 10163-383) that reflects the

risk mitigation proposed by the Agency, EPA is now rescinding the cancellation order. The ID

will account for any comments received on the PID as well as the amended label submitted by

Gowan.

The cancellation order for EPA Registration Nos. 10163-382 and 10163-383 is hereby

rescinded.

Authority: 7 U.S.C. 136 et seq.

Dated: June 15, 2022.

Mary Elissa Reaves,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

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